IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	CIVIL NO. _____
	)	
v.	)	
	)	
WILDERNESS FAMILY NATURALS, LLC, a limited liability company, and KENNETH H. FISCHER, and ANNETTE C. FISCHER, individuals,	)	COMPLAINT FOR PERMANENT INJUNCTION
	)	
Defendants.	)	

INTRODUCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin and restrain Wilderness Family Naturals, LLC ("Wilderness Family"), a limited liability company, and Kenneth H. Fischer and Annette C. Fischer, individuals (hereinafter, collectively, "Defendants") from violating:

A. 21 U.S.C. § 331(d), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p) that are neither approved under 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i);

B. 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate

commerce articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

C. 21 U.S.C. § 331(k), by causing articles of drug to become misbranded, within the meaning of 21 U.S.C. § 352(f)(1) while held for sale after shipment in interstate commerce.

JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331 and 1345.

3. Venue in this District is proper pursuant to 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

4. Defendant Wilderness Family has been organized as a limited liability company under the laws of the State of Minnesota since May 2005, and has been in operation for approximately six years. The firm conducts business at 99 Edison Boulevard, Suite 1, Silver Bay, Minnesota, within the jurisdiction of this Court. The firm manufactures and/or distributes a wide variety of products including, but not limited to, coconut products (i.e., oil, milk, cream, water, vinegar, flour, and bath and body products), products they describe as "healthy foods," herbs, salves, vitamins, minerals, and "essential oils."

5. Kenneth H. Fischer and his wife, Annette C. Fischer, are co-owners of Wilderness Family. Mr. Fischer is the company's

chief executive officer and Ms. Fischer is its president. Both Mr. and Ms. Fischer share ultimate authority and responsibility for the day-to-day operations of the firm and oversight of employees' activities. Specifically, they are responsible for, and have authority over, product development, labeling and promotional materials, advertising, product packaging, accounting, procurement, and development of the content of the firm's website, www.wildernessfamilynaturals.com ("WFN website"). Mr. and Ms. Fischer maintain offices at the Edison Boulevard address, and Ms. Fischer also maintains an office at their home, 70 Garden Drive, Silver Bay, Minnesota.

LEGAL STANDARDS

6. Under the Act, a product is a drug if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1)(B).

7. Under the Act, a "new drug" is any drug "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . ." 21 U.S.C. § 321(p)(1).

8. The Act defines labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any

of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). The Supreme Court has held that the term "accompanying" in the second clause of § 321(m) is not restricted to labels that are on or in the article at issue and that physical attachment is not necessary; rather, the Court has held that an article "accompanies" another when one supplements or explains the other, such as a committee report of the Congress "accompanies" a bill. Kordel v. United States, 335 U.S. 345, 350 (1948).

9. Under the Act, a new drug may not be introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application or an abbreviated new drug application with respect to the drug, or it qualifies for an exemption as an investigational new drug. 21 U.S.C. § 355.

10. The introduction or delivery for introduction into interstate commerce of an unapproved new drug is a violation of the Act, 21 U.S.C. § 331(d).

11. A drug is misbranded if its labeling fails to bear "adequate directions for use." 21 U.S.C. § 352(f)(1). "Adequate directions for use" is defined at 21 C.F.R. § 201.5 to mean directions under which a layman can use a drug safely and for the purposes for which it is intended

12. The introduction or delivery for introduction into interstate commerce of any drug that is misbranded is a violation of the Act, 21 U.S.C. § 331(a).

13. The causing of a drug to become misbranded while held for sale after shipment in interstate commerce is a violation of the Act, 21 U.S.C. § 331(k).

DEFENDANTS' BUSINESS

14. Defendants have been and are now engaged in making claims that their products cure, mitigate, treat, and/or prevent various diseases. Specifically, Defendants promote the use of their products on websites owned and/or controlled by Defendants, and/or referenced by, endorsed, or adopted directly or indirectly by Defendants, for the cure, mitigation, treatment, and/or prevention of various diseases including, but not limited to, cancer, diabetes, heart disease, hyperthyroidism, chronic fatigue syndrome, HIV/AIDS, and arthritis.

15. Many of Defendants' products are drugs within the meaning of the Act, 21 U.S.C. § 321(g)(1)(B), because the products' labeling and promotional materials establish that Defendants' products are intended to be used in the cure, mitigation, treatment, and/or prevention of disease.

16. Defendants' drug products are new drugs within the meaning of 21 U.S.C. § 321(p)(1), because they are not generally recognized, among experts qualified by scientific training and

experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling.

17. There is not now, nor has there ever been, an approved new drug application or an abbreviated new drug application on file with the FDA for any of Defendants' drugs, nor do Defendants' drugs qualify for an exemption as investigational new drugs. Accordingly, Defendants' drugs are unapproved new drugs, within the meaning of 21 U.S.C. § 355.

18. Defendants' drugs are misbranded within the meaning of 21 U.S.C. § 352(f)(1), because their labeling fails to bear adequate directions for use, indeed many fail to bear any directions for use, and, as unapproved new drugs, they are not exempt from the requirements of 21 U.S.C. § 352(f)(1).

INTERSTATE COMMERCE

19. Defendants distribute their products to customers throughout the United States.

20. Defendants receive raw ingredients from suppliers, both foreign and domestic, outside the state of Minnesota.

DEFENDANTS' HISTORY AND CLAIMS FOR THEIR PRODUCTS

21. Defendants sell several products for which they make claims, either on the products' labels or on one or more of three websites, listed in paragraphs 23 and 25, that cause the products to be drugs within the meaning of the Act.

22. FDA inspected Defendants' facility between May 9 and May 11, 2005. Following that inspection, FDA issued a Warning Letter to Defendants explaining that claims made on product labels and on their websites, www.wildernessfamilynaturals.com ("WFN website") and www.regaininghealthnaturally.com ("RHN website") caused certain of Defendants' products to be drugs, including but not limited to:

- Coconut Oil, Extra Virgin
- Extra Virgin Centrifuge Extracted Coconut Oil
- Extra Virgin Traditional Philippine Coconut Oil
- Flax Hull Lignans
- Green Food Feast
- Chest Rub Salve
- Goldenseal-Comfrey Salve

The Warning Letter stated that failure to take prompt action to correct violations may result in enforcement action being initiated without further notice, including injunction.

23. Defendants responded to the Warning Letter through counsel, by letter dated November 29, 2005. In that letter, Defendants' counsel represented that Defendants would "remov[e] from its websites (www.wildernessfamilynaturals.com and www.regaininghealthnaturally.com) and product labels all claims that expressly or implicitly associate any of [its] products with disease."

24. In January 2006, www.healthinformationlibrary.com ("HIL website") was launched.

25. During an FDA inspection conducted from December 7-9, 2006, Ms. Fisher claimed to have "given away" the RHN and the HIL websites.

26. During a subsequent inspection from November 26-30, 2007, FDA documented that product labels and the WFN, RHN, and/or HIL websites continued to promote Defendants' products for the cure, mitigation, treatment, and prevention of various diseases. During the 2007 inspection, Ms. Fischer stated to the FDA investigator that the WFN website had been "sanitized" for FDA.

27. Despite the foregoing warnings and inspections, Defendants continue to own, control, or reference, endorse, or adopt claims made on various websites from which customers can get information about their products: the WFN website, from which products can be purchased, the RHN website, and the HIL website. The three websites continue to interact extensively, including maintaining active hyperlinks that direct users among the three, listing the same telephone contact number on each cite, and containing textual references to Wilderness Family. These websites contain numerous claims that certain of Defendants' products can be used to cure, treat, mitigate, and/or prevent various diseases including, but not limited to, cancer, diabetes,

heart disease, hyperthyroidism, chronic fatigue syndrome, HIV/AIDS, and arthritis.

28. Currently, Defendants continue to promote their products as drugs by making claims on the products' immediate labels and/or on one or more of the three websites described above. The drug products and diseases for which they are being offered include:

- St. John's Wort Salve - promoted for use for boils, burns, inflammatory skin disease, putrid leg ulcers, cuts, hard tumors, and conjunctivitis
- Chickweed Salve - promoted for use for diaper rash and chicken pox
- Goldenseal-Comfrey Salve - promoted for use for infection generally
- Chest Rub Salve - promoted for use for upper respiratory infections
- Flax Hull Lignans - promoted for use for cancer prevention and as having antiviral, antibacterial, and antifungal properties
- Green Food Feast Powder - promoted for use for cancer, diabetes, bleeding disorders, gout, arthritis, anemia, and hypothyroidism
- Extra Virgin Certified Organic Centrifuged Extracted Coconut Oil - promoted for use for cancer, heart

disease, HIV/AIDS, diabetes, chronic fatigue syndrome, hypothyroidism, high cholesterol, high blood pressure, fibromyalga, ulcers, Candida, herpes, allergies, psoriasis, influenza, and Crohn's Disease

- Extra Virgin Traditional Philippine Process Coconut Oil - promoted for use for cancer, heart disease, HIV/AIDS, diabetes, chronic fatigue syndrome, hypothyroidism, high cholesterol, high blood pressure, fibromyalga, ulcers, Candida, herpes, allergies, psoriasis, influenza, and Crohn's Disease
- Expeller Pressed Coconut Oil - promoted for use for cancer, heart disease, HIV/AIDS, diabetes, chronic fatigue syndrome, hypothyroidism, high cholesterol, high blood pressure, fibromyalga, ulcers, Candida, herpes, allergies, psoriasis, influenza, and Crohn's Disease.

29. The claims summarized in paragraph 28 and detailed further in Exhibit A, attached hereto, cause Defendants' products, St. John's Wort Salve, Chickweed Salve, Goldenseal-Comfrey Salve, Chest Rub Salve, Flax Hull Lignans, Green Food Feast Powder, Extra Virgin Certified Organic Centrifuged Extracted Coconut Oil, Extra Virgin Traditional Philippine Process Coconut Oil, and Expeller Pressed Coconut Oil to be drugs within the meaning of the Act, 21 U.S.C. § 321(g)(1).

30. Defendants' history of promoting products to cure, mitigate, treat, and/or prevent the risk of diseases including, but not limited to, cancer, diabetes, heart disease, hyperthyroidism, chronic fatigue syndrome, HIV/AIDS, and arthritis, demonstrates their unwillingness to comply with the Act. Based on Defendants' continued course of conduct, it is evident that, unless restrained by order of this Court, Defendants will continue to distribute unapproved new drugs and misbranded drugs in violation of the Act, 21 U.S.C. § 331(a), (d), and (k).

WHEREFORE THE PLAINTIFF PRAYS:

I. That Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, be permanently restrained and enjoined from directly or indirectly: (a) introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce unapproved new drugs in violation of 21 U.S.C. § 331(d); (b) introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce misbranded drugs in violation of 21 U.S.C. § 331(a); and (c) causing any article of drug to become misbranded while held for sale after

shipment in interstate commerce in violation of 21 U.S.C. § 331(k); and

II. That Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, be permanently restrained and enjoined from introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce any product unless and until: (a) an approved new drug application or abbreviated new drug application filed pursuant to 21 U.S.C. § 355(b) or (j) is effective with respect to the product; (b) an effective investigational new drug exemption filed pursuant to 21 U.S.C. § 355(i) is in effect for the product; or (c) Defendants have removed all claims from their product labels, labeling, promotional materials, websites owned or controlled by or related to Defendants, and in any other media that cause that product to be a drug, within the meaning of the Act, and cease to reference, endorse, or adopt, directly or indirectly, other websites or media that contain claims that cause Defendants' products to be drugs, within the meaning of the Act.

III. That Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

DATED this 3rd day of December, 2008

Respectfully submitted,

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